REMARKS

In response to the Office Action dated October 31, 2008, the Applicant respectfully requests consideration of the following remarks.

Claims 16-24, 38 and 39 are pending in the current application and were rejected under 35 USC 103(a) as obvious over U.S. Patent No. 4,994,033 to Shockey, *et al.* ("Shockey") in view of U.S. Patent No. 5,447,497 to Sogard, *et al.* ("Sogard"). In response to this rejection, the Applicant respectfully submits the following remarks.

Applicant's invention as recited in claim 16 recites a process for treating tissue using an elongate flexible catheter. The catheter has a flexible treatment sheath that "is formed of an elastic material" and a dilatation balloon "formed of a substantially inelastic material." Claim 16 recites the step of "while maintaining the dilatation balloon in an unexpanded condition, supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact;" and the step of "while maintaining the treatment sheath in said substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue."

In contrast to Applicant's invention, the Shockey reference does not disclose using different materials for the inner and outer members, much less different materials as claimed in the Applicant's claims. Shockey discloses an expander member 22 and an inner sleeve 30. Shockey does not state, suggest or even hint at making the expander member 22 and the inner sleeve 30 of different materials, much less making the expander member 22 and the inner sleeve 30 of different materials such that the expander member can be fairly characterized as "elastic" in comparison to a substantially inelastic inner sleeve.

The Sogard reference does not provide any suggestion or reason for modifying Shockey to meet Applicant's claims. Sogard is directed to a dual layered balloon catheter. Sogard does not disclose or suggest delivering a treatment fluid between the balloon layers or provide any

teaching from which a person of ordinary skill in the art would think to modify Shockey to somehow come up with Applicant's invention.

Nevertheless, claim 16 has been amended above to recite that the step of "supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact" occurs "while maintaining the dilatation balloon in an unexpanded condition." Support for this limitation can be found in the specification at paragraph [0063] as follows:

> The administration of the therapeutic agent while dilatation balloon 24 is evacuated (FIG. 7) improves the therapy in several respects, as compared to prior arrangements in which the dilatation balloon must be inflated to force the therapeutic agent radially outward through a perforated delivery balloon. First, the flow rate of therapeutic agent through the sheath is more effectively controlled by direct control of the fluid pressure of the therapeutic agent, rather than indirect control through expansion of the dilatation balloon. The much lower pressures at which the agent is administered improve control and avoid arterial wall damage from "jetting". Secondly, the evacuated dilatation balloon occupies less space within compartment 52, leaving a larger proportion of the compartment volume occupied by the therapeutic agent. This results in more uniform fluid pressure (of the agent) throughout compartment 52, and avoids unwanted localized contact of the dilatation balloon with radially inward portions of the sheath. This leads to a more uniform flow of the agent through the sheath into tissue.

The Applicant respectfully submits that the invention as recited in claim 16 is neither anticipated nor rendered obvious by the references. In fact, in Shockey, the reference explicitly states that it is only with expansion of the inner sleeve 30 that the device is forced into contact with the vessel wall:

> Once the distal end of the catheter is appropriately positioned with the aid of a radiopaque marker band 46, the selected drug or other material is introduced through the proximal port 40 and through the lumen 32 and into the confines of the outer expander member 22. The injection of the drug will cause some enlargement of the outer expander member 22 but typically the pressure at which the drug material is injected is below the point where substantial

> amounts of the drug are ejected out through the micropores 28. To perform the simultaneous substance delivery and dilatation, an inflation fluid is next injected through the port 42 and thence through the lumen 34 into the interior of the expander sleeve 30. As the pressure is increased, typically approaching seven to ten atmospheres, the expander member inflates to its predetermined maximum diameter and, in doing so, forces the liquid substance through the ports 28 to effectively spray the lesion being treated with a particular drug or other material. The expansion of the inner sleeve 30 also results in pressure being exerted against the lesion, forcing it against the vessel wall as the drug or other substance is delivered. The combination of the dilatation pressure and the drug substance release will been found to be effective in providing long-term patency to the treated blood vessel.

(Shockey, col. 3, line 67-col. 4, line 24).

The Applicant respectfully submits that neither Sogard nor any of the other references of record provides any reason for modifying Shockey to meet Applicant's claims. In fact, a modification of Shockey to perform the step of "supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact" while "maintaining the dilatation balloon in an unexpanded condition" would be directly contrary to the explicit sequence of operation that Shockey describes as "effective in providing long-term patency to the treated blood vessel." Thus, Shockey teaches away from any such modification to meet Applicant's claims.

In view of the foregoing, the Applicant respectfully requests favorable reconsideration of this application and allowance of all claims. Should any questions arise, the Examiner is invited to call the undersigned at the number given below. The Commissioner is hereby authorized to charge any fees and credit any overpayments associated with this filing to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,

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